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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/650,005	08/28/2000	Glenn F. Osborne	25527-0005	7486

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EXAMINER

LU, TOM Y

ART UNIT	PAPER NUMBER
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2621

DATE MAILED: 05/06/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/650,005

Applicant(s)

OSBORNE ET AL.

Examiner

Tom Y Lu

Art Unit

2621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment and written response filed on February 25, 2004 has been entered.
2. Claims 22 and 24 are cancelled.
3. Claims 25-30 are added.
4. Claims 1-21, 23 and 25-30 are pending.

Response to Arguments

5. Applicant's arguments with respect to claims 1, 21 and 23 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-21, 23 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caple et al (WO 99/04043) in view of Kuga et al (U.S. Patent No. 5,936,078).

- a. Referring to Claim 1, Caple discloses CPU (note CPU herein is recognized as a computer network, which includes multiple machines, provides services of web server, database server and application server, page 10, line 7) communicates with one user facility (the user facility is a laboratory, page 9, line 22), configured to perform a group of functions comprising receiving and transmitting test results (page 9, line 36) related to said patient (patient with Alzheimer's disease or other

disease, page 9, lines 1-20), supporting data analysis (page 10, line 21), and providing security (any communication within a network contains basic encryption, which is considered to be security) and business functions (page 11, lines 27-33); CPU is configured to perform a group of functions comprising storing data test result, clinical information associated with test result, personal medical history information related to the patient, treatments suitable for diagnosed conditions related to test result, data related information, and statistical information associated with test result (page 10, lines 10-20); CPU is also configured to recognize a diagnostic master user corresponding to a user facility and a diagnostic user corresponding to an individual patient associated with said diagnostic master user, to facilitate information exchanged between the Web server and the database server, and to perform a group of functions comprising statistical comparison and analysis between test result related to the patient received by the Web server, test parameters, personal medical history information supplied by the database server, diagnosing a physiological condition of the patient suggested by the statistical comparison and analysis, and recommending methods of treatment for said patient based on the physiological condition (the facilities, such laboratories act as the claimed "master diagnostic user", individual patients are the claimed "individual patient"). However, Caple does not explicitly disclose the test result is hybridization information even though Caple does point out at page 10, line 19, stored data in the database can be DNA data or sequence listing. Kuga at column 3, lines 47-49, teaches finding the treatment for

Alzheimer's disease by comparing the results of the hybridization information using an image analyzer, which Kuga provides hybridization information that Caple lacks, and comparing the information with DNA sequences stored in a database. At the time the invention was made, a person of ordinary skill in the art would have been motivated to input hybridization information as test data in Caple's system because both Caple and Kuga teaches using DNA sequences to find treatment for Alzheimer's disease, and Caple at page 20, states his system welcomes modifications and substitutions.

- b. Referring to Claim 2, the combination of Caple and Kuga teaches wherein the group of functions performed by said web server further comprises functions selected from the group consisting of product information, product ordering, company information, statistical summary of patient database, request to the application server and security (Caple: page 14, lines 1-21, page 15, lines 25-26).
- c. Referring to Claim 3, Caple teaches wherein the data stored by the database server further comprises data selected from the group consisting of genetic pattern database data for chip ID, patient genetic pattern database, and statistical data summary data (Caple: page 13, line 32, page 10, lines 7-9 and 19-20).
- d. Referring to Claim 4, the combination of Caple and Kuga teaches wherein the application server constructs at least one query for the database server, and performs at least one statistical comparison between hybridization parameter received by the web server and hybridization parameter supplied by the database server (Caple: page 11, lines 27-32).

- e. Referring to Claim 5, the combination of Caple and Kuga teaches wherein the application server is further configured to perform functions selected from the group of functions consisting of data query for chip ID genetic pattern, database query for statistical data summary, pattern match statistical processing, and results output (Caple: page 13, line 32, page 10, lines 7-9 and 19-20).
- f. Referring to Claim 6, the combination of Caple and Kuga teaches an operation server (Caple: page 11, line 21).
- g. Referring to Claim 7, the combination of Caple and Kuga teaches wherein the operations server comprises functions selected from the group consisting of order management, billing management, and order tracking (Caple: page 11, line 21).
- h. Referring to Claim 8, the combination of Caple and Kuga teaches wherein the user facility is linked to said artificial intelligence system through encrypted network connection (see explanation in Claim 1 for encryption, and the laboratory is linked with CPU through cable or phone line).
- i. Referring to Claim 9, the combination of Caple and Kuga teaches wherein the user facility is a remote user facility.
- j. Referring to Claim 10, the combination of Caple and Kuga teaches wherein the user facility is a local user facility.
- k. Referring to Claim 11, the combination of Caple and Kuga teaches wherein the user facility is selected from the group consisting of a hospital, a clinic, a research facility, a business, and a non-profit organization (Caple teaches it can be laboratory).

- l. Referring to Claim 12, the combination of Caple and Kuga teaches wherein an optical scanning system to collect hybridization signals from a nucleic acid array, an image processing system to convert optical data from the optical scanning system into a set of hybridization parameters, a computer linked to a network; and a user interface to display data related information (Kuga discloses using an image analyzer to analyze the results of the hybridization, column 3, lines 47-49, such is also described in Caple's, page 9, lines 26, which is linked to CPU).
- m. Referring to Claim 13, the combination of Caple and Kuga teaches the network is the Internet (Caple: page 10, line 4).
- n. Referring to Claim 14, the combination of Caple and Kuga teaches the group of functions consisting of manipulating data, search data, analyzing data, and displaying data (Caple: page 15, lines 3-6).
- o. Referring to Claim 15, the combination of Caple and Kuga teaches wherein the user interface further comprises displayed information selected from the group consisting of user information (page 13, line 16, PIN), clinical sample information (page 13, line 10, sample collection), testing information (page 13, line 20, test result), clinical information (page 13, line 22, patient history), results report for biopharma chip, therapeutic choices, and billing information (page 13, lines 35-37).
- p. Referring to Claim 16, the combination of Caple and Kuga teaches wherein the data related information is selected from the group consisting of hybridization information (Kuga: column 3, line 45), patient information, statistical

information, clinical information, medical information, diagnosis information, treatment information, biological information, product information, and company information (Caple: page 13, lines 7-37).

- q. Referring to Claim 17, the combination of Caple and Kuga teaches wherein the user facility further comprises functions selected from the group consisting genetic pattern processing (Caple: sequence listings, page 10, line 19), request for pattern match for chip ID and report generation (Caple: unique bar-coded ID, page 13, line 21).
- r. Referring to Claim 18, the combination of Caple and Kuga teaches a computer linked to a network (Caple: page 10, line 3, CPU); and a user interface to display data related information (Caple: page 10, line 5, display).
- s. Referring to Claim 19, the limitations are addressed in Claim 16.
- t. Referring to Claim 20, the combination of Caple and Kuga teaches a system architecture based on a shared processing functionality between at least one remote location and at least one central data processing facility (Caple: figure 1).
- u. With regard to Claim 21, the only difference between Claim 1 and Claim 21 is Claim 21 calls for additional limitations of “a patient identifier related to said patient”, Caple at page 13, line 16, teaches personal identification numbers for patients.
- v. With regard to Claim 23, the only difference between Claim 21 and Claim 23 is Claim 23 calls for collecting information from a “proteomics chip”, which Kuga at column 3, line 45, teaches cDNA probes.

- w. With regard to Claim 25, the only difference between Claim 21 and Claim 25 is Claim 25 calls for “living organism”, which a patient is a living organism.
- x. With regard to Claim 26, the combination of Caple and Kuga does not explicitly teach the living organism is an animal. However, it is well known in the art that all living beings, such as human beings, animals and plants, contains DNA sequences, which the combination of Caple and Kuga teaches analyzing DNA sequences to find treatments for a particular disease, such as Alzheimer’s disease. In addition, as Caple at page 20, lines 5-7, teaches it is understood to that various modifications and substitutions can be made to the system, which a person of ordinary skill in the art would have been motivated to modify Caple’s system to perform analysis for an animal.
- y. With regard to Claim 27, the combination of Caple of Kuga can be modified to perform analysis on a plant, the motivation is provided in Claim 26.
- z. With regard to Claim 28, see explanation in Claims 23 and 25.
- aa. With regard to Claim 29, see explanation in Claim 26.
- bb. With regard to Claim 30, see explanation in Claim 27.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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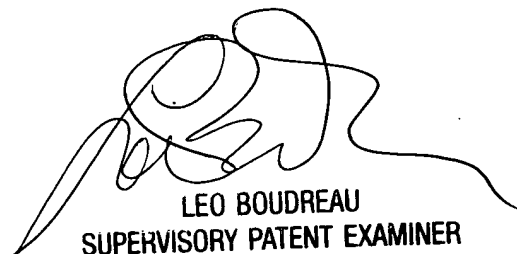
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y Lu whose telephone number is (703) 306-4057. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tom Y. Lu



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